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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/505,347	08/19/2004	Jeffrey S Kiel	455-020	7386
1009 KING & SCHIO	7590 03/28/200 CKLI, PLLC	8	EXAMINER	
247 NORTH B	ROADWAY		SHEIKH, HUMERA N	
LEXINGTON, KY 40507			ART UNIT	PAPER NUMBER
			1618	
			MAIL DATE	DELIVERY MODE
			03/28/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

	Application No.	Applicant(s)				
Office Action Comments	10/505,347	KIEL ET AL.				
Office Action Summary	Examiner	Art Unit				
	Humera N. Sheikh	1618				
The MAILING DATE of this communication ap Period for Reply	pears on the cover sheet with the c	correspondence address				
A SHORTENED STATUTORY PERIOD FOR REPL WHICHEVER IS LONGER, FROM THE MAILING D - Extensions of time may be available under the provisions of 37 CFR 1. after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period - Failure to reply within the set or extended period for reply will, by statut Any reply received by the Office later than three months after the mailin earned patent term adjustment. See 37 CFR 1.704(b).	DATE OF THIS COMMUNICATION 136(a). In no event, however, may a reply be tin will apply and will expire SIX (6) MONTHS from e, cause the application to become ABANDONE	N. nely filed the mailing date of this communication. D (35 U.S.C. § 133).				
Status						
1) Responsive to communication(s) filed on 19 A	August 2004					
,— · · · · · · · · · · · · · · · · · · ·	s action is non-final.					
<i>,</i>	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is					
,	closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.					
Disposition of Claims						
4)⊠ Claim(s) <u>1-27</u> is/are pending in the application						
,—	4a) Of the above claim(s) is/are withdrawn from consideration.					
5) Claim(s) is/are allowed. 6) Claim(s) is/are rejected.						
7) Claim(s) is/are rejected.						
8) Claim(s) is/are objected to:	election requirement					
o) Claim(s) 1-27 are subject to restriction and/or	election requirement.					
Application Papers						
9)☐ The specification is objected to by the Examiner.						
10)☐ The drawing(s) filed on is/are: a)☐ acc	cepted or b)⊡ objected to by the I	Examiner.				
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).						
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.						
Priority under 35 U.S.C. § 119						
 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some coll None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. 						
Attachment(s) 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date	4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal F 6) Other:	ate				

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DETAILED ACTION

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Status of the Application

Claims 1-27 are pending in this action. Claims 1-27 are subject to an Election/Restriction requirement.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-8, 19, 22 and 23, drawn to a therapeutic composition.

Group II, claim(s) 9-16, 20, 24 and 25, drawn to a therapeutic composition.

Group III, claim(s) 17, 18, 21, 26 and 27, drawn to a therapeutic composition.

The inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The Group I composition is distinct from the Group II composition in that the Group I composition does not require the substantial absence of decomposition products, as does the Group II composition. The Group I composition is distinct from the Group III composition in that the Group II composition does not have to be prepared using the process steps required in the Group III composition does not have to be prepared using the process steps required in the Group III composition does not have to be prepared using the process steps required in the Group III composition.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

If Applicant chooses to elect <u>Group I</u>, then the following election of species is required:

The species are as follows:

1. Election of Organic Solvent:

- (a) alcohol; isopropyl alcohol; ethanol
- (b) mineral oil
- (c) glycerin
- (d) propylene glycol

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

Species (a) corresponds to claims 2, 4 & 7; Species (b) corresponds to claim 3; Species (c) corresponds to claim 5; Species (d) corresponds to claim 6.

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The following claim(s) are generic: claim 1.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: The species (a)-(d) utilize physically and/or chemically

distinct elements which would be capable of imparting different results and effects.

* * * * *

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as

to form a single general inventive concept under PCT Rule 13.1.

If Applicant chooses to elect <u>Group II</u>, then the following election of species is required:

The species are as follows:

2. Election of Decomposition Product:

- (a) benzhydrol
- (b) benzophenone
- (c) diphenylchloromethane
- (d) dimethylaminoethanol
- (e) diphenylmethane
- (f) diphenyl alkyl ether

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

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Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

Species (a) corresponds to claim 10; Species (b) corresponds to claim 11; Species (c) corresponds to claim 12; Species (d) corresponds to claim 13; Species (e) corresponds to claim 14; Species (f) corresponds to claim 15.

The following claim(s) are generic: claim 9.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: The species (a)-(f) utilize physically and/or chemically distinct decomposition products which would impart various effects if contained in the composition.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

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invention to be rejoined.

application. Any amendment of inventorship must be accompanied by a request under 37 CFR

1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. <u>All</u> claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

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Because the above restriction/election is complex, a telephone call to applicants to

request an oral election was not made. See MPEP 812.01.

Correspondence

Any inquiry concerning this communication or earlier communications from the

examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604.

The examiner can normally be reached on Monday, Tuesday, Thursday and Friday during

regular business hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Michael Hartley, can be reached on (571) 272-0616. The fax phone number for the

organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent

Application Information Retrieval (PAIR) system. Status information for published applications

may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

applications is available through Private PAIR only. For more information about the PAIR

system, see http://pair-direct.uspto.gov. Should you have any questions on access to the Private

PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Humera N. Sheikh/

Primary Examiner, Art Unit 1618

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